Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D1102217	09/29/2023
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric Center Of Southwest Louisiana, The	2800 Country Club Road, Lake Charles, LA	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A Recertification survey was conducted September 29, 2023 at The Pediatric Center of Southwest Louisiana, CLIA ID # 19D1102217. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual and proficiency test (PT) records and interview with personnel, the laboratory failed to maintain a complete policy for proficiency testing. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not include instructions for review and documentation of PT evaluation results that are ungraded and/or educational. 2. Review of the laboratory's PT records revealed the laboratory did not document review of Wisconsin State Laboratory of Hygiene (WSLH) 2023 HemeReg1 sample XIE6 with result status "not scored - non consensus referee." 3. In interview on September 29, 2023 at 10 a.m., Personnel 2 confirmed the laboratory did not have a policy for review of ungraded and/or educational PT evaluation results.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling,

	storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on observation, review of the manufacturer's instructions for use and the laboratory's policy and procedure manual, as well as interview with laboratory personnel, the laboratory failed to establish a complete policy for complete blood count testing. Findings: 1. Observation by surveyors during the laboratory tour on September 29 at 9:27 a.m. revealed the laboratory utilized the Medonic M Series for complete blood count testing. 2. Review of the manufacturer's Medonic M Series instructions for use revealed "System Information Messages" that defined the instrument flags. 3. Review of the laboratory's policy "Manual Differential Criteria" revealed the laboratory's criteria for performing a manual differential included "Any WBC with an instrument 'OM' code" but did not include all instrument flags and the corresponding action(s) the laboratory should perform. 4. In interview on September 29, 2023 at 11:50 a.m., Personnel 2 confirmed the laboratory's policy did not identify all manufacturer flags and the action to take if such flags occur.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: ***Repeat deficiency from survey conducted on March 23, 2022*** Based on observation; review of the laboratory's Individualized Quality Control Plan (IQCP), control records, and patient test records; as well as interview with personnel, the laboratory failed to perform quality control (QC) for Group A B-hemolytic Streptococcus (Bacteriology) testing per their IQCP for one (1) of eight (8) months reviewed. Findings: 1. Observation by surveyors during the laboratory tour on September 29, 2023 at 9:27 a.m. revealed the laboratory utilized the Quidel Solana

	GAS Assay for Group A B-hemolytic Streptococcus testing. 2. Review of the laboratory's IQCP for the Solana GAS Assay revealed "It is recommended that the reactivity of each new lot and each new shipment of the Solana GAS Assay be verified on receipt and before use and every 30 days." 3. Review of the laboratory's QC records revealed the laboratory did not perform QC at least every 30 days in July 2023: - QC performed June 13, 2023 - QC performed July 20, 2023 4. Review of the laboratory's patient test records revealed the following patients were tested on the Solana GAS Assay between July 14, 2023 and July 20, 2023 without QC: - Chart #104090 - Chart #284100 - Chart #270520 - Chart #303130 - Chart #285110 - Chart #264760 - Chart #273290 - Chart #331900 5. In interview on September 29, 2023 at 1pm, Personnel 2 confirmed QC was not performed every thirty days as while Personnel 4 was on vacation.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory's Quality Assurance monitors failed to identify and correct quality issues. Refer to D5445.
D6005	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(c) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (c) The laboratory director must be accessible to the laboratory to provide onsite, telephone or electronic consultation as needed. This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS 209 form (Laboratory Personnel Report) and personnel records as well as interview with personnel, the Laboratory Director failed to delegate, in writing, the responsibilities of Technical Consultant. Findings: 1. Review of the laboratory's CMS 209 form (Laboratory Personnel Report) revealed Personnel 2 and Personnel 4 were listed as the Technical Consultants. 2. Review of personnel records revealed the laboratory did not have documentation of the Laboratory Director delegating the tasks and responsibilities of Technical Consultant to Personnel 4. 3. In interview on September 29, 2023 at 10:45am, Personnel 2 confirmed the laboratory did not have documentation of the Laboratory Director delegating the tasks and responsibilities of Technical Consultant to Personnel 4.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)

	The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: ***Repeat deficiency from survey conducted on March 23, 2022*** Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality control program was maintained to assure the quality of laboratory testing. Refer to D5445.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was established and maintained to assure the quality of laboratory services provided. Findings: 1. The laboratory failed to maintain a complete policy for proficiency testing. Refer to D5291. 2. The laboratory's Quality Assurance monitors failed to identify and correct quality issues. Refer to D5793.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure an approved policy and procedure manual was available to all personnel. Refer to D5403.